transient corneal opacity may occur following the administration of this product.''

(l) All labels for autogenous biologics shall bear the following statement: ''Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist.''

(m) In the case of biological products containing Marek's disease virus, all labels shall specify the Marek's disease virus serotype(s) used in the product.

(Approved by the Office of Management and Budget under control number 0579–0013)

[38 FR 12094, May 9, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §112.7, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§112.8 For export only.

The applicable regulations for packaging and labeling a biological product produced in the United States shall apply to such biological product if exported from the United States except as otherwise provided in this section. Only labels approved as provided in §112.5 shall be used.

(a) Biological products which have been packaged and labeled for export or which have been exported, shall be subject to the applicable provisions in this paragraph.

(1) After leaving the licensed establishment, a biological product shall not be bottled, repackaged, relabeled, or otherwise altered in any way while in the United States; and

(2) An exported biological product shall not be returned to the United States: *Provided*, That, in the case of a biological product exported in labeled final containers, the Administrator may authorize by permit the importation of a limited number for research and evaluation by the producing licensee; and

(3) An exported biological product which is bottled, rebottled, or altered in any way in a foreign country shall not bear a label which indicates by establishment license number that it has been prepared in the United States.

(b) Desiccated and frozen liquid products, packaged and labeled as for domestic use, may be exported without the diluent required for rehydration or dilution, as the case may be, if the labeling includes adequate instructions for preparing the product for use and the words ''For Export Only''.

(c) Final containers of products, labeled or unlabeled, may be exported in sealed shipping boxes, adequately identified as to contents with an approved label, and plainly marked ''For Export Only'': *Provided*, That such products shall not be diverted to domestic use.

(d) Completed inactivated liquid products, antiserums, and antitoxins, may be exported in large multiple-dose containers identified with an approved label that contains the words ''For Export Only'' prominently displayed.

(e) Concentrated inactivated liquid product, completed except for dilution to the proper strength for use, may be exported in large multiple-dose containers identified with an approved label that contains the words ''For Export Only'' prominently displayed.

[38 FR 12094, May 9, 1973, as amended at 39 FR 19202, May 31, 1974; 40 FR 46093, Oct. 6, 1975; 43 FR 11145, Mar. 17, 1978; 56 FR 66784, Dec. 26, 1991]

§112.9 Biological products imported for research and evaluation.

A biological product imported for research and evaluation under a permit issued in accordance with §104.4, with the exception of products imported under §104.4(d), shall be labeled as provided in this section.

(a) The label shall identify the product and the name and address of the manufacturer and shall provide instructions for proper use of the product, including all warnings and cautions needed by the permittee to safely use the product.

(b) Labels on each product to be further distributed in accordance with §103.3 shall bear the statement ''Notice! For Experimental Use Only—Not for Sale!''

(c) The labeling shall contain any other information deemed necessary by the Administrator and specified on the permit.

[50 FR 46417, Nov. 8, 1985, as amended at 56 FR 66784, Dec. 26, 1991]